NORTH DAKOTA
DEPARTMENT of HEALTH

DIVISION OF DISEASE CONTROL
Medical Services Section
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MEMO

TO: Prevention Partnership Providers and
Local Public Health Units

FROM: Molly Sander
Immunization Program Manager

RE: Hib Vaccine Shortage

DATE: December 21, 2007

Merck Hib vaccine recall:

On December 13, 2007, Merck & Co., Inc. announced a voluntary recall of certain lots of two *Haemophilus influenzae* type b (Hib) conjugate vaccines, PedvaxHIB® and Comvax® (Hib/hepatitis B vaccine). Some state-supplied PedvaxHIB® was included in this recall. Providers may also have private doses of recalled vaccine. The affected doses were distributed beginning in April 2007. Additional information regarding the affected lots is available online from the Food and Drug Administration (FDA) at www.fda.gov/consumer/updates/hib121307.html.

No potency concerns have been identified for these recalled vaccine lots. Individuals who received vaccine from these lots should complete their immunization series with a Hib-containing vaccine not affected by this recall, but **do not need to be revaccinated** to replace a dose they received from a recalled lot.

Information about how to return recalled lots of Merck Hib vaccine is being sent to providers. Procedures for returning recalled vaccine are also outlined on the Merck website at www.merckvaccines.com/PCHRecall.pdf. Providers may also call Stericycle directly at 800.643.0240 to coordinate the return of recalled Hib vaccines.

Hib vaccine shortage:

Merck has suspended production of its Hib conjugate vaccines and does not expect to resume distribution of these vaccines until the fourth quarter of 2008. The recall of PedvaxHIB and Comvax, along with the suspension of production are expected to result in short-term disruption to the Hib vaccine supply in the United States.

Two other Hib conjugate vaccines, manufactured by sanofi pasteur, are currently licensed and available for use in the United States. ActHIB® and TriHIBit® (DTaP/Hib vaccine) are unaffected by the recall. However, due to an expected increase in demand, sanofi pasteur likely will not be able to immediately provide adequate Hib vaccine to fully vaccinate all children for whom the vaccine is recommended.

Because of the short-term reduction in available doses of Hib-containing vaccines, CDC recommends that **providers temporarily defer administering the routine Hib vaccine booster dose administered at age 12–15 months <u>except to children in specific groups at high risk</u>**. Providers should register and track children for whom the booster dose is deferred to facilitate recalling them for vaccination when supply improves.

Children at high-risk include those with:

- **asplenia**
- **sickle cell disease**
- **human immunodeficiency virus infection and certain other immunodeficiency syndromes**
- **malignant neoplasms**

CDC recommends that providers continue to vaccinate these children with available Hib conjugate vaccines according to the routinely recommended schedules, including the 12–15 month booster dose. PedvaxHIB® (if available), ActHIB®, and TriHIBit® may be used for the booster doses for these children during this shortage.

American Indian/Alaska Native (AI/AN) children are also at increased risk for Hib disease, particularly in the first 6 months of life. Compared with sanofi pasteur Hib vaccines, the administration of Merck Hib vaccines leads to a more rapid seroconversion to protective antibody concentrations within the first 6 months of life. **CDC recommends that providers who currently use PedvaxHIB® and/or Comvax® to serve predominantly AI/AN children in AI/AN communities continue to stock and use <u>only</u> Merck Hib vaccines, not affected by the recall, and vaccinate according to the routinely recommended schedules, <u>including the 12–15 month booster dose</u>.**

CDC has provided the North Dakota Department of Health (NDDoH) with an allocation of PedvaxHIB® for its Native American population. Until further notice, providers may order state-supplied PedvaxHIB® for Native American children only. Orders will be reviewed by NDDoH staff and compared to the North Dakota Immunization Information System (NDIIS) doses administered data for Native American children.

If a Native American child presents for Hib vaccination and Merck Hib vaccine is unavailable, that child should preferably be referred to a clinic with Merck Hib vaccine on hand (i.e., IHS). If this is not possible, the child should be vaccinated with sanofi pasteur Hib vaccine.

The NDDoH will be supplying sanofi pasteur ActHIB® vaccine until further notice for vaccination of all other North Dakota children. TriHIBit® will no longer be available for order from the NDDoH because the NDDoH will not be receiving an allocation of TriHIBit® from CDC.

<u>Ordering information:</u>

- Any Hib orders placed prior to December 12 that have not been received were cancelled by CDC and should be reordered from the NDDoH.
- Any Hib orders placed from December 13 – 19 were not accepted by the NDDoH and should be reordered.
- All orders will be accepted by the NDDoH based on doses administered reports.

<u>REMINDER: As of January 1, 2008, providers must have private supplies of vaccine to vaccinate insured children, as the NDDoH will only supply vaccine for Vaccines For Children</u>

(VFC) eligible children. Providers must order private Hib vaccine from sanofi pasteur. Private vaccine may be ordered by calling sanofi pasteur at 1-800-VACCINE.

The NDDoH has confirmed with Blue Cross Blue Shield (BCBS) that providers who have private Hib vaccine on hand may administer private vaccine to BCBS insured children and bill BCBS. Providers should bill the vaccine and administration on two separate lines: one with the vaccine CPT code and charges for the serum, and one with the immunization administration CPT (90465-90474) and charges for the administration. The NDDoH does not have information from other insurance companies, so it is the provider's choice whether or not to administer private vaccine to non-BCBS children and bill insurance. Private Hib vaccine may also be given to Medicaid children and Medicaid can then be billed. Due to the nature of their current system, Medicaid claims may initially be denied. For any questions on the Medicaid billing process, please contact Barb Koch at 328.1044.

Hib vaccine information:

PedvaxHIB® is a three-dose series at 2, 4, and 12 -15 months of age. ActHIB® is a four-dose series at 2, 4, 6, and 12-15 months of age. TriHIBit® may only be used for the booster dose of the Hib series at 12 – 15 months of age. **TriHIBit® can be used if the child is 12 months of age or older and has received at least one prior dose of Hib vaccine two or more months earlier and TriHIBit® will be the last dose in the Hib series.** TriHIBit® is not approved for use as the primary series at 2, 4, or 6 months of age. If TriHIBit® is used for one of the doses of the primary series, the Hib doses should be considered invalid, and the child should be revaccinated as age-appropriate for Hib.

Hib disease information:

A Hib fact sheet is available at www.ndhealth.gov/Immunize/Disease/.

For more information about the shortage, please see the following Morbidity and Mortality Weekly Report: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm56d1219a1.htm.

As always, please feel free to contact the NDDoH Immunization Program with any questions or concerns at 701.328.3386 or toll-free at 800.472.2180.